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(54) A VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTATING SUCH VALVE PROSTHESIS.

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Description

Background of the Invention.

The present invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastical valve which is mounted on an elastical stent wherein the commissural points of the elastical collapsible valve are mounted on the cylinder surface of the elastical stent.

Valve prostheses of this type are usually implanted in one of the channels of the body to replace a natural valve. In the present description the invention will be explained in connection with an cardiac valve prosthesis for implantation in aorta. However, it will be possible to use a valve prosthesis according to the invention in connection with implantation in other channels in the body by using the same technique as the one used for implantation of cardiac valve prosthesis. Such an implantation may e.g. comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
2. a valve in the oesophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

An existing natural valve in the body is traditionally replaced with a valve prosthesis by a surgical implantation. However, a surgical implantation is often an exacting operation. Thus, today the implantation of cardiac valves are solely made by surgical technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for extern circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

Due to its exacting character it is impossible to offer such operation to certain people. For instance this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in US Patent specifications Nos. 3,671,979 and 4,056,854. However, both these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

From US Patent specification No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prosthesis is not designed for implantation in the body by catheterization. Even though the Patent specification contains no detailed explanation the description indicates that this valve prosthesis is designed for implantation and sewering on by a surgical intervention.

Moreover, from the US Patent specifications Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

The nearest prior art may be that described in GB-A-2,056,023. This document discloses an elastic stent as described by way of introduction. Thus this stent described comprises an elastic collapsible valve being mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible it will not be suited for implantation by a catheterization procedure.

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure this can for instance be grate shaped, loop shaped or helical. This makes is possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may e.g. be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon. When using a self-expandable stent a catheter with an expansion ar-

rangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small which makes it possible to introduce the valve prosthesis through a channel in the body.

When the valve prosthesis is introduced and placed correctly the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an outer dimension which is slightly larger than the channel in which it is placed. As the stent is elastic a contraction of the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention to optionally expose the body channel, e.g. a vein, through which the insertion takes place. Thus patients for whom operation will be associated with high risk can be offered implantation of for instance cardiac valves. After the implantation has taken place the after-treatment will advantageously be shorter than normally which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implantate the valve prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves. The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the central veins in the centre of the leg towards the superficial veins. Among other things this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumours, where too much humour is produced. If the humour is able to flow from the cancerous tumour through several channels it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prostheses.

When the valve prosthesis is used as cardiac valve prosthesis in the aorta it is possible to mount it in three positions, viz. in the descending part of the aorta, in a position between the coronary arteries and the left ventricle of the heart or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who can not be offered an open heart surgery the valve prosthesis can also be used for patients in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who can not be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.

Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prosthesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries it is desirable that the valve prosthesis has a greater surface to distribute the

outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implantating a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with a profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implantating cores in the body are known. For instance such balloon catheters are known from US Patent specifications Nos. 4,856,516, 4,733,665 and 4,796,629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvatageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevent a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for the catheter, X-ray supervision, injection of X-ray tracable liquids, ultrasonic measuring etc. may be used.

Description of the Drawings.

The invention will now be explained in details with reference to the accompanying schematical drawing, wherein

- Fig. 1 shows a perspective view of a stent without a valve,
- Fig. 2 a perspective view of a valve prosthesis according to the invention made from the stent shown in Fig. 1 having a biological valve mounted thereon,
- Fig. 3 a partiel view through the aorta illustrating a partially inflated balloon catheter,
- Fig. 4 a cross section through the embodiment shown in Fig. 3,
- Fig. 5-7 views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,
- Fig. 8-10 views illustrating three possible positions of a cardiac valve prosthesis, and
- Fig. 11-12 perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall.

Fig. 1 shows a stent 1 made by support means in the form of two 0,55 mm surgical stainless steel wires 2,3. The wires are folded in 15 loops. Three loops 4 are 14 mm in height and intended to secure the commissural points 5 (see Fig. 2) from a biological cardiac valve 6 which is mounted in the stent 1. The remaining loops have a height of 8 mm. Each of the two folded wires 2,3 was bended to form rings 7,8 which were closed by welding the ends. The two rings are place on the top of each other as will appear from Fig. 1 and they are mutually secured by means of a number of sutures (not shown). By using a substantially cylindrical thread structure with projecting apices a reduction in weight is obtained compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve 6 was removed from a slaughtered pig of 100 kg. The valve was cleaned before mounting in the stent 1. The cleaned valve has an outer diameter of 25-27 mm and the height of the three commissural points 5 is 8 mm. The valve 6 is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis 9 shown in Fig. 2. The valve prosthesis produced is used for performing tests in pigs by implantation of cardiac valve prosthesis. However, the cardiac valve prosthesis for use in human beings has a corresponding form.

Fig. 3 shows a partial view through the aorta 10. A balloon catheter 11 is introduced in the aorta according to the direction of an arrow 12. In the Figure shown the balloon means 13 of the balloon catheter is led out of the protection cap 11A and is partly inflated through a fluid channel 15, which is led to the surface of the patient. The balloon means 13 constitutes a tri-sectional balloon upon which the cardiac valve prosthesis is placed. In the form shown the cardiac valve prosthesis is expanded exactly to be in contact with the aorta 10. The balloon means 13 is provided with three projecting beads 14 which are engaged with the one side of the cardiac valve prosthesis 9. The blood flowing through the aorta according to the direction of an arrow 16 will thus cause the cardiac valve prosthesis 9 to abut on the beads 14 and the valve cannot be displaced in relation to the balloon means 13. Moreover, the balloon catheter used

comprises a central channel 17 to receive a guide wire 18 which is used in a way known per se for supervising the introduction of the catheter through fluoroscopi. In the shown embodiment beads 14 are only used at one side of the valve prosthesis, but, however, it will often be desirable to use the beads in pairs placed along lines parallel to the longitudinal axes 19 through the balloon means 13. In this case the spacing of the pair of beads 14 will correspond to the height of the loops of the stent. This makes it possible to make an effective fastening of a valve prosthesis on balloon means. Moreover, the fastening on the balloon means may be provided by using balloon means with an indentation in the surface (not shown).

Fig. 4 shows a cross section through the embodiment shown in Fig. 3 illustrating the placing of the beads 14 on the tri-sectional balloon means 13.

A balloon catheter of the above described type which was used in tests of implantating the cardiac valve prosthesis 9 in pigs had the following dimensions. Each of the three balloons is 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons is 31 mm and in the balloon catheter used two beads 14 having a height of 3 mm are mounted on each side of the three balloons. The beads have a spacing of 15 mm. The protection cap 11A of the balloon catheter has an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter is provided with a standard guide wire having a diameter of 0.9 mm and a length of 300 cm.

Figs. 5-7 show the valve prosthesis 9 at different steps in introducing and implantating in the aorta 10 by means of the catheter 11 having the inflatable balloon means 13. The cardiac valve prosthesis 9 is initially placed above the deflated balloon means 13 and compressed manually around the balloon means (Fig. 5), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning the balloon means 13 is inflated (Fig. 6) thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter 11 may subsequently be removed from the aorta 10 (Fig. 7). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter 13. When the valve prosthesis is mounted as showed in Fig. 7 the patient will be able to resume a substantially normal life after a few days.

Figs. 8-10 show the positioning of the valve prosthesis 9 as cardiac valve prosthesis in the aorta 10 in three different positions. In a position between the coronary arteries 20 and the left ventricle of the heart 21 (Fig. 8). In a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (Fig. 9). In a position in the descending part of the aorta 10. The positioning of the valve prosthesis is chosen in accordance with the diagnose of the illness of the patient. By placing the cardiac valve prosthesis as shown in Fig. 8 there is a risk of detachment and/or covering the mouth of the coronay arteries, and therefore it is preferred to use a higher stent which for instance comprises several rings 7,8 placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. Fig. 8 and 9 show how a contrast medium 23 is injected by means of a so-called pigtail catheter for registration of the tightness of the implantated valve prosthesis 9.

A specific embodiment for a valve prosthesis and a balloon catheter for implantating the valve prosthesis has been explained above. However, it is obvious that it is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g. polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in Figs. 11 and 12. In both Figures the support means of the valve prosthesis is made of an elongated tubular means 24 having a closed cylinder surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against the wall of the channel. In Fig. 11 the valve 6 is mounted at the end of the tubular means 24. In Fig. 12 an embodi-

ment is showed where the valve 6 is mounted in a central position in the tubular means 24.

An explanation of a method of implantating a valve prosthesis according to the invention is given below:

- a valve prosthesis 9 made of a stent 1 and a collapsible valve 6, as described above,
- the valve prosthesis 9 is placed on a deflated balloon means and is manually compressed thereon,
- the balloon means 13 and the valve prosthesis are drawn into an insertion cover 11A,
- a guide wire 18 is inserted into the left ventricle of the heart through the central opening 17 of the balloon catheter under continuous fluoroscopi,
- the insertion cover 18 conveys the guide wire 18 to a point in the channel in immediate vicinity of the desired position of the valve prosthesis,
- the balloon means 13 is pushed out of the protection cap 11A and the valve prosthesis is positioned in the desired position if necessary by use of further registration means to ensure an accurate positioning,
- the balloon means 13 is inflated with a certain overstretching of the channel,
- the balloon means 13 is deflatated, and
- the balloon means 13, the guide wire 18 and the protection cap 11A are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be closed.

Claims

1. A valve prosthesis (9), preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastical valve (6) which is mounted on an elastical stent (1) wherein the commissural points (5) of the elastical collapsible valve (6) are mounted on the cylinder surface of the elastical stent (1), **characterized** in that the stent is made from a radially collapsible and re-expandable cylindrical support means (7,8,24) for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

2. A valve prosthesis according to claim 1, **characterized** in that the support means (7,8) is made of a thread structure (2,3).

3. A valve prosthesis according to claim 2, **characterized** in that the thread structure (2,3) comprises several spaced apices projecting from the one side of the cylindrical structure and in direction along the longitudinal axis of the cylinder and that the commissural points (5) of the valve (6) are attached to the projecting apices.

4. A valve prosthesis according to claim 3, **characterized** in that the elastically collapsible valve (6) is a biological trilobate valve.

5. A valve prosthesis according to claim 4, **characterized** in that the stent (1) is made from a stainless steel wire (2,3) folded in a number of loops (4) and bended according to a circle and welded to form a closed ring (7,8), that the stent comprises two or more such closed rings which are mutually connected end to end to form the cylindrical thread structure (2,3), that three of the loops (4) in the external ring are folded with a greater height than the remaining loops to form the apices to which the commissural points of the biological valve are attached.

6. A valve prosthesis according to claim 5, **characterized** in that each of the rings (7,8) of the stent (1) is made from a wire having a diameter of 0.55 mm and a loop height of approximately 8 mm and approximately 14 mm for the three greater loops, and that the cylindrical thread structure produced and the collapsible valve mounted thereon in a folded state have an outer diameter of approximately 10 mm and in expanded state an outer diameter of approximately 30 mm.

7. A valve prosthesis according to claim 5, **characterized** in that three or more mutually attached rings (7,8) placed on top of each other are used and that the stent (1) is made to be fixed through the expansion at one point in the channel where the valve prosthesis is inserted, which point is different from the point where the valve is mounted in the stent.

8. A valve prosthesis according to any of the preceding claims, **characterized** in that the cylinder surface of the support means is closed to form a tubular element (24).

9. A balloon catheter (11) for use in implantating a valve prosthesis (9) according to any of the preceding claims and comprising a channel (15) for injection of a fluid for the inflation of the balloon means (13) of the catheter and an insertion cap (11A) wherein the balloon means (13) of the catheter and a collapsible valve prosthesis (9) mounted thereon are located during the injection, **characterized** in that the balloon means (13) are provided with a profiled

surface (14) which is made to ensure a steady fastening of the valve prosthesis (9) during the withdrawal of the balloon means (13) from the protection cap (11A) and the subsequent inflation for expanding the stent (1).

10. A balloon catheter according to claim 9, **characterized** in that the profiling of the surface is made by beads (14) or buds on the surface of the balloon means.

11. A balloon catheter according to claim 10, **characterized** in that the beads (14) are placed in pairs in a number from four to eight along lines parallel with the longitudinal axis (19) of the balloon means and with a spacing corresponding to the height of the stent (1) used.

12. A balloon catheter according to claim 9, **characterized** in that the profiling of the surface is made by an indentation which is formed in the surface of the balloon means (13) with an extension corresponding to the height of the stent (1) used.

Patentansprüche

1. Klappenprothese (9), vorzugsweise eine Herzklappenprothese, zur Implantation im Körper, die eine zusammendrückbare elastische Klappe (6) umfaßt, welche auf einem elastischen Stent (1) angebracht ist, bei der die Kommissurpunkte (5) der elastischen zusammendrückbaren Klappe (6) auf der Zylinderoberfläche des elastischen Stent (1) angebracht sind, dadurch gekennzeichnet, daß der Stent zum Zusammenfalten und Aufweiten zusammen mit der zusammendrückbaren Klappe für eine Implantation im Körper mittels einer Katheterisierungstechnik aus einer in radialer Richtung zusammendrückbaren und wiederaufweitbaren zylindrischen Haltevorrichtung (7,8,24) besteht.

2. Klappenprothese nach Anspruch 1, dadurch gekennzeichnet, daß die Haltevorrichtung (7,8) aus einer Fadenstruktur (2,3) besteht.

3. Klappenprothese nach Anspruch 2, dadurch gekennzeichnet, daß die Fadenstruktur (2,3) mehrere in einem Abstand angeordnete spitzen umfaßt, die aus der einen Seite der zylindrischen Struktur und in Richtung entlang der Längsachse des Zylinders überstehen, und daS die Kommissurpunkte (5) der Klappe (6) an den überstehenden Spitzen angebracht sind.

4. Klappenprothese nach Anspruch 3, dadurch gekennzeichnet, daß die elastisch zusammendrückbare Klappe (6) eine biologische dreilappige Klappe ist.

5. Klappenprothese nach Anspruch 4, dadurch gekennzeichnet, daß der Stent (1) aus einem Draht (2,3) aus rostfreiem Stahl hergestellt ist, der in einer Anzahl von Schleifen (4) gefaltet und kreisförmig gebogen und zusammengeschweißt ist, so daß er einen geschlossenen Ring (7,8) bildet, daß der Stent zwei oder mehr derartige geschlossene Ringe umfaßt, die Ende an Ende miteinander verbunden sind, um die zylindrische Fadenstruktur (2,3) zu bilden, daß drei der Schleifen (4) im äußeren Ring mit einer größeren Höhe ausgebildet sind als die übrigen Schleifen, um die Spitzen zu bilden, an denen die Kommissurpunkte der biologischen Klappe angebracht sind.

6. Klappenprothese nach Anspruch 5, dadurch gekennzeichnet, daß jeder der Ringe (7,8) des Stent (1) aus einem Draht mit einem Durchmesser von 0,55 mm und einer Schleifenhöhe von ungefähr 8 mm und ungefähr 14 mm bei den drei größeren Schleifen hergestellt ist und daß die erzeugte zylindrische Fadenstruktur und die daran angebrachte zusammendrückbare Klappe in einem zusammengefalteten Zustand einen Außendurchmesser von ungefähr 10 mm und im aufgeweiteten Zustand einen Außendurchmesser von ungefähr 30 mm aufweisen.

7. Klappenprothese nach Anspruch 5, dadurch gekennzeichnet, daß drei oder mehr miteinander verbundene Ringe (7,8) verwendet werden, die übereinander angeordnet sind, und daß der Stent (1) so hergestellt ist, daß er durch die Aufweitung an einem Punkt in dem Kanal, in den die Klappenprothese eingeführt wird, fixiert wird, wobei dieser Punkt von dem Punkt verschieden ist, an dem die Klappe im Stent angebracht ist.

8. Klappenprothese nach irgendeinem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß die Zylinderoberfläche der Haltevorrichtung geschlossen ist, so daß ein tubusförmiges Element (24) gebildet wird.

9. Ballonkatheder (11) zur Verwendung beim Implantieren einer Klappenprothese (9) nach irgendeinem der vorangehenden Ansprüche, der einen Kanal (15) zur Injektion eines Fluids zum Aufpumpen der Ballonvorrichtung (13) des Katheters und eine Einführkappe (11A) umfaßt, in

der die Ballonvorrichtung (13) des Katheters und eine darauf angebrachte zusammendrückbare Klappenprothese (9) während der Injektion untergebracht sind, dadurch gekennzeichnet, daß die Ballonvorrichtung (13) mit einer profilierten Oberfläche (14) versehen ist, die hergestellt ist, um ein beständiges Festhalten der Klappenprothese (9) während des Zurückziehens der Ballonvorrichtung (13) aus der Schutzkappe (11A) und des anschließenden Aufpumpens zur Aufweitung des Stent (1) sicherzustellen.

10. Ballonkatheder nach Anspruch 9, dadurch gekennzeichnet, daß das Profil der Oberfläche aus Wülsten (14) oder Knospen auf der Oberfläche der Ballonvorrichtung besteht.

11. Ballonkatheder nach Anspruch 10, dadurch gekennzeichnet, daß die Wülste (14) paarweise in einer Anzahl von vier bis acht entlang von Linien angebracht sind, die parallel zur Längsachse (19) der Ballonvorrichtung verlaufen, und mit einem Abstand, der der Höhe des verwendeten Stent (1) entspricht.

12. Ballonkatheder nach Anspruch 9, dadurch gekennzeichnet, daß die Profilierung der Oberfläche durch eine Einkerbung hergestellt wird, die in der Oberfläche der Ballonvorrichtung (13) mit einer der Höhe des verwendeten Stent (1) entsprechenden Erstreckung ausgebildet ist.

Revendications

1. Prothèse de valvule (9), de préférence prothèse de valvule cardiaque, pour implantation dans le corps et comprenant une valvule élastique (6) pouvant s'affaisser, montée sur un appui ("Stent") élastique (1), dans laquelle les points commissuraux de la valvule élastique pouvant s'affaisser sont montés sur la surface cylindrique de l'appui élastique, caractérisée en ce que l'appui est constitué d'un moyen support (7, 8, 24) cylindrique et pouvant s'affaisser radialement et se redéployer, pour se plier et se déployer conjointement avec la valvule élastique, et permettre l'implantation dans le corps au moyen d'une technique de cathétérisation.

2. Prothèse de valvule selon la revendication 1, caractérisée en ce que le moyen support (7, 8) est une structure à fil (2, 3).

3. Prothèse de valvule selon la revendication 2, caractérisée en ce que la structure à fil (2, 3) comprend plusieurs sommets espacés faisant saillie depuis un côté de la structure cylindrique, s'étendant dans la direction de l'axe longitudinal du cylindre et les points commisuraux (5) de la valvule (6) sont fixés aux sommets en saillie.

4. Prothèse de valvule selon la revendication 3, caractérisée en ce que la valvule (6) pouvant s'affaisser élastiquement est une valvule trilobée biologique.

5. Prothèse de valvule selon la revendication 4, caractérisée en ce que l'appui (1) est constitué d'un fil en acier inoxydable (2, 3) plié en un certain nombre de boucles (4) et cintré suivant un cercle et soudé pour constituer un anneau fermé (7, 8), l'appui comprenant deux ou plusieurs de ces anneaux fermés reliés mutuellement bout à bout pour constituer la structure cylindrique à fil (2, 3), trois de ces boucles (4) dans l'anneau externe sont pliées avec une hauteur supérieure à celle des boucles subsistantes, pour former les sommets auxquels sont fixés les points commissuraux de la valvule biologique.

6. Prothèse de valvule selon la revendication 5, caractérisée en ce que chacun des anneaux (7, 8) de l'appui (1) est constitué d'un fil de 0,55 mm de diamètre et la hauteur de boucle étant d'à peu près 8 mm et d'à peu près 14 mm pour les trois boucles plus grandes, et en ce que la structure cylindrique à fil produite et la valvule effaçable montée sur elle ont, à l'état plié, un diamètre extérieur d'à peu près 10 mm et, à l'état déplié, un diamètre extérieur d'à peu près 30 mm.

7. Prothèse de valvule selon la revendication 5, caractérisée en ce que trois anneaux (7, 8) ou plus, mutuellement reliés et placés l'un sur l'autre sont utilisés et l'appui (1) est réalisé pour être fixé par l'expansion en un point dans le canal dans lequel la prothèse de valvule est insérée, ce point étant différent du point où la valvule est montée dans l'appui.

8. Prothèse de valvule selon l'une quelconque des revendications précédentes, caractérisée en ce que la surface cylindrique du moyen support est fermée pour constituer un élément tubulaire (24).

9. Cathéter à ballon (11), pour utilisation dans l'implantation d'une prothèse de valvule (9) selon l'une quelconque des revendications précédentes, et comprenant un canal (15) pour injection d'un fluide destiné à gonfler le moyen

formant ballon (13) du cathéter et un capuchon d'insertion (11A), dans lequel le moyen formant ballon (13) du cathéter et une prothèse de valvule pouvant s'affaisser (9) montée dessus sont placés pendant l'injection, caractérisé en ce que les moyens formant ballon (13) sont pourvus d'une surface (14) profilée réalisée pour assurer une fixation permanente de la prothèse de valvule (9) pendant l'extraction des moyens formant ballon (13) du capuchon de protection (11A) et le gonflage subséquent destiné à déployer l'appui (1).

10. Cathéter à ballon selon la revendication 9, caractérisé en ce que le profilage de la surface est constitué de grains (14) ou boutons disposés à la surface des moyens formant ballon.

11. Cathéter à ballon selon la revendication 10, caractérisé en ce que les grains (14) sont placés par paires, en un nombre allant de quatre à huit, sur des lignes parallèles à l'axe longitudinal (19) des moyens formant ballon et avec un espacement correspondant à la hauteur de l'appui (1) utilisé.

12. Cathéter à ballon selon la revendication 9, caractérisé en ce que le profilage de la surface est constitué d'une indentation formée dans la surface des moyens à ballon (13), avec une extension correspondant à la hauteur de l'appui (1) utilisé.

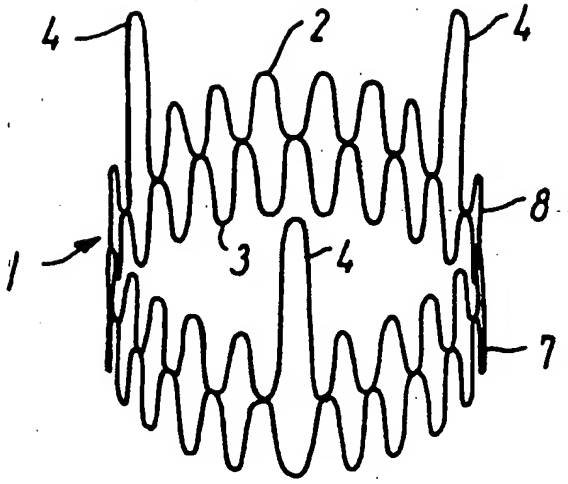

FIG.1

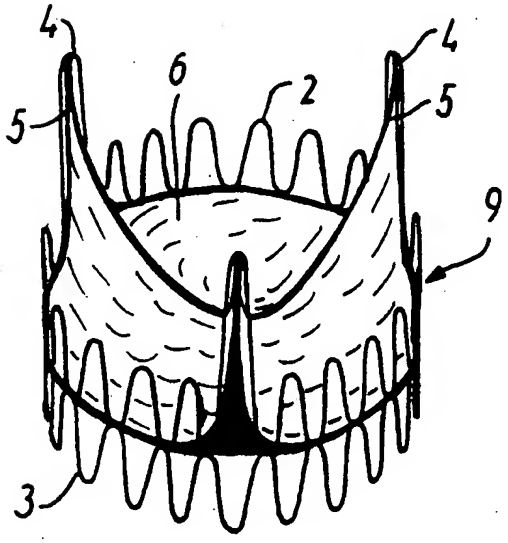

FIG.2

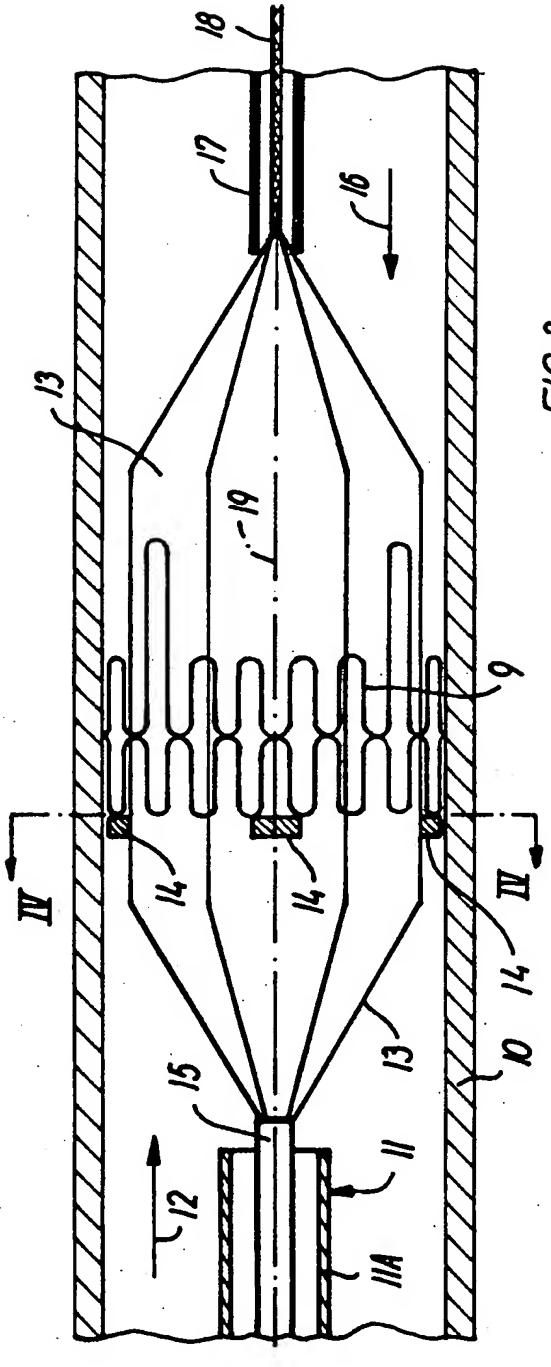

FIG.3

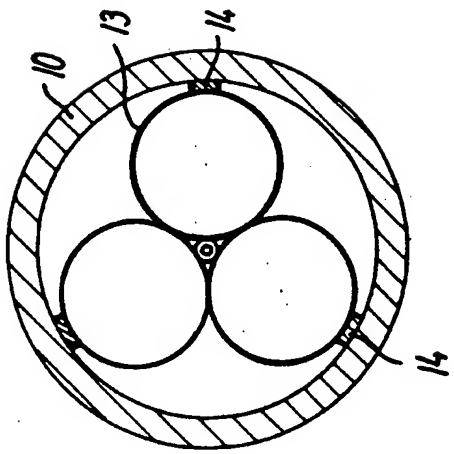

FIG.4

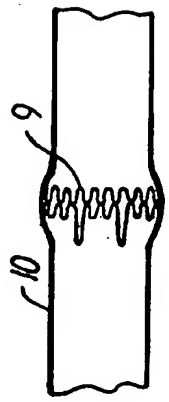

FIG.7

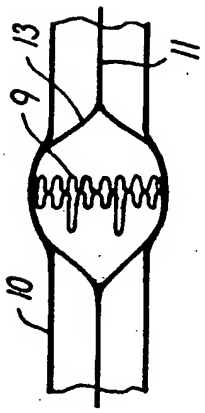

FIG.6

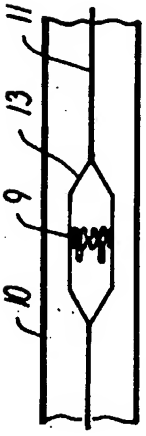

FIG.5

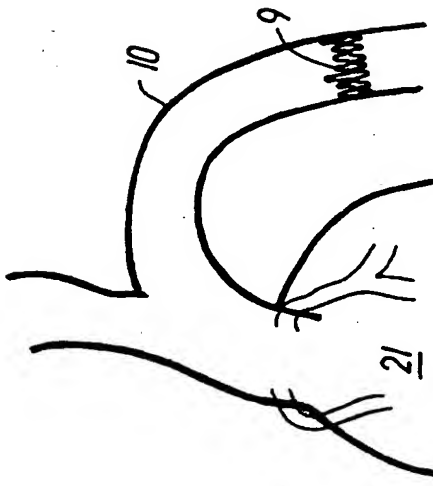

FIG.10

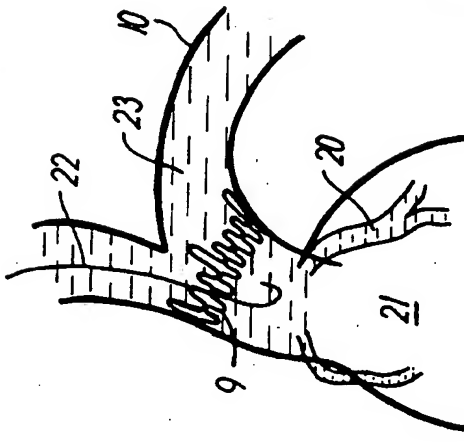

FIG.9

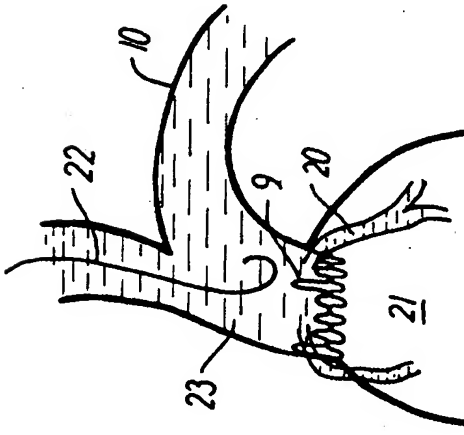

FIG.8

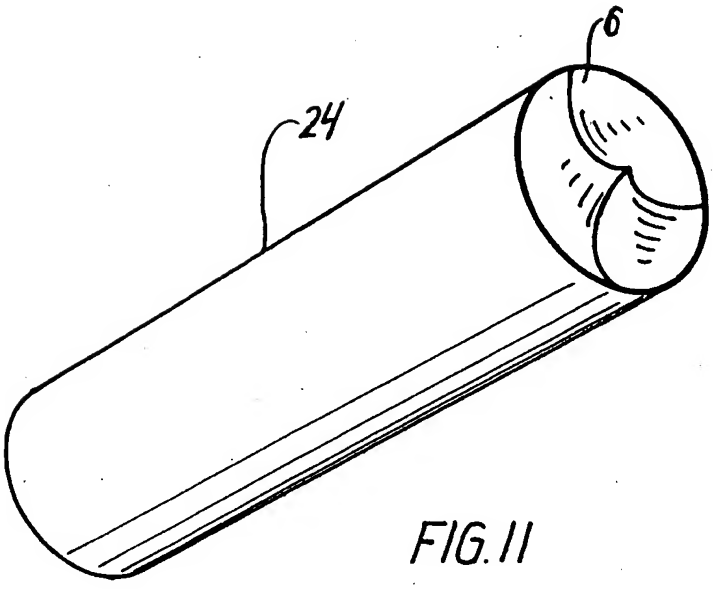

FIG. 11

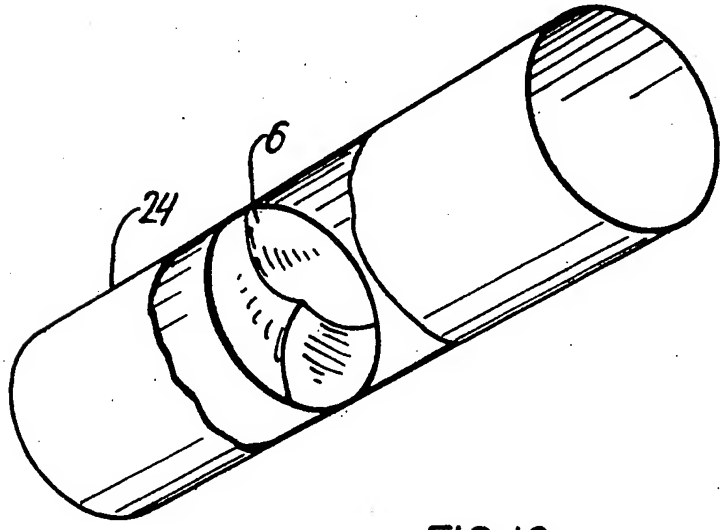

FIG. 12